

## REMARKS

### Election/Restriction:

Applicants acknowledge the Examiner's entry of the restriction requirement.

### Finality of the Rejection:

Applicants note the Examiner's entry of a final rejection on the first Office Action. Applicants submit that this final rejection is premature. MPEP 706.07(c).

Pursuant to MPEP 706.07(b), the Examiner may finally reject claims in a first Office Action only if "all claims of the new application (1) are drawn to the same invention claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application." (emphasis added). Because neither of these conditions is met here, the finality of the rejection is premature.

First, the rejected claims are not "drawn to the same invention claimed in the earlier application." Prior to the first Office Action, Applicants cancelled all of the then-pending claims and submitted new claims 45-64. These new claims do not recite features that were recited in the claims in the earlier application. For example, independent claims 45 and 58 do not recite barbs "extending in a generally transverse direction from a longitudinal axis of the stent," nor do they recite a wire orientation step. See e.g., cancelled claims 21 and 31. Further, as submitted, independent claims 45 and 48 recite structural features that were not recited in the claims of the earlier application. For example, independent claims 45 and 58 as submitted require a wire that is "bent to form ... [a] bend." Because these new claims are not "drawn to the same invention claimed in the earlier application," they cannot be finally rejected in a first Office Action. MPEP 706.07(b).

Second, none of claims 45-64, as submitted in the present application, was or would have been properly finally rejected on the grounds and art cited by the Examiner.

For example, as explained below in greater detail, the cited art does not disclose a stent having all of the recited structural features, including a wire stent having an integrally formed barb, and that is bent to form a bend, so that the barb points in a predetermined direction. In contrast, the cited art recites structures with non-integrally formed barbs and/or structures with unbent apices. A wire that is bent to form a bend has plastically deformed bend regions, unlike structures with unbent apices. Bending may induce strains in the wire that weaken or otherwise affect the characteristics of the stent. Consequently, a wire that is bent to form a bend has distinctive structural characteristics over stent wires that do not have such bends.

Applicants filed a Request for Continued Examination, paid the required fee, and submitted new claims that are distinguishable over the art of record. Accordingly, the finality of the rejection is premature. Applicants respectfully request that the Examiner withdraw the finality of the rejection.

#### **In the Claims:**

Claims 45, 46, 48-50, 53, 58, and 60-62 are currently pending in this application. Applicants have amended Claims 45 and 58 to more particularly emphasize the novelty of the claimed invention. No new matter has been added by virtue of these amendments. Support for the amendments may be found throughout the specification, and especially in paragraphs 198-206.

Independent claims 45 and 58 are drawn to stents made from wire and having integrally formed barbs. As mentioned in the background section of the present application, one of the issues in the prior art is that, in use, the barbs on a wire stent can separate from the wire due to internal body forces acting on the stent, such as cyclical loading caused by cardiovascular pulsatile forces. Such forces can cause mechanical fatigue and failure at the barb-stent junction. See e.g., ¶¶17-20.

Wire stents with non-integral barbs may be prone to fracture, detachment, and the like, because the junction between the wire and the barb acts as a stress concentrator and because the chemically and/or mechanically-modified junction has a tendency to corrode when subjected to a saline, oxygen-rich physiological environment.

See e.g., ¶¶18-19. Similarly, wire stents with barbs that are oriented by bending or plastically deforming the barb may also be susceptible to mechanical fatigue and failure because bending the barb can induce undesirable strains in the stent that weaken the barb-stent junction. See e.g., ¶¶17-20 and 198-206.

The presently claimed invention addresses these problems by providing a wire stent with an integral barb that points in a predetermined direction. In contrast with the prior art, where such a barb is pointed by bending or plastically deforming the barb with respect to the wire, here, the at least one barb is unbent, and is free of weakening due to bending. See e.g., Claims 45 and 58.

Such a stent is structurally distinct over prior art wire stents. First, the barb and the wire are integral and “have not been attached to the stent wire during the manufacturing process.” See e.g., ¶ 5. Consequently, stents as claimed may be less prone to corrosion and fracture, and will be better able to accommodate and distribute bending and shear stresses via the barb. See e.g., ¶19. Second, the barb is unbent and is not plastically deformed, or weakened, like prior art barbs. Consequently, the barb-stent junction may be stronger, and such stents may be less prone to barb separation due to mechanical fatigue.

The prior art of record does not disclose a stent as recited in each of the claims of the present application. Accordingly, Applicants assert that these claims are allowable and respectfully request notice to this effect.

### **Claim Rejections under 35 USC § 102(e)**

The Examiner rejected claims 45, 46, 48-50, 53, 58, and 60-62 under 35 USC § 102(e) as anticipated by U.S. Patent No. 6,849,087 (“Chuter”).

Chuter does not teach or disclose a stent with all of the structural features recited in the rejected claims. In particular, the rejected claims are drawn to a wire stent having an integrally formed barb, where the wire is bent to form a bend, so that the barb points in a predetermined direction. In contrast, Chuter recites structures with non-integrally formed barbs (see e.g., Chuter, figure 7a; col. 8, lines 51-54 (“[h]ooks 90 may be connected to each proximal apex by welding or gluing or other suitable connecting

means,”)) and structures with apices that are not bent, but instead are cut in a pattern from a cylinder (see e.g., *id.*, figure 7b; col. 8, lines 55-59).

The Examiner is mistaken in his contention that the bending limitation regards a product by process step and further that the prior art “show[s] the final structure implied by [bending],” because bending imparts “distinctive structural characteristics” that stent wires that are not “bent to form . . . [a] bend” do not possess. See MPEP 2113 (citing to *In re Garnero*, 412 F.2d 276, 279; 162 USPQ 221, 223 (CCPA, 1979), holding that 1) the limitation “interbonded . . . by interfusion,” like the limitations “press fitted,” “etched,” and “welded,” is a structural limitation, rather than a process limitation; and 2) prior art that did not disclose an apparatus with the claimed structural characteristics did not invalidate the claims at issue).

Indeed, a stent wire that is “bent to form . . . [a] bend” has distinctive structural characteristics over stent wires that do not have such bends, for example, because bending results in plastic deformation of the wire in the bend region. Consequently, bending may induce strains in the wire that weaken or otherwise affect the mechanical and functional characteristics of the stent. See e.g., ¶¶17-20 and 198-206. In contrast, the pattern of the attachment system shown in figure 7b of Chuter is cut in shape from a cylinder (Chuter, col. 8, lines 55-59) and thus does not have plastically deformed bend regions. Therefore, the apices 93, 94 of the structure shown in FIG 7b of Chuter are structurally distinct from the bends as recited in the claims submitted in the present application.

In order to anticipate under § 102, an asserted reference must teach or disclose each and every element of the claimed invention. MPEP § 2131. Because the stents recited in rejected claims 45 and 58 have structural features that are not taught or disclosed by Chuter, and because claims 46, 48-50, and 53 depend directly or indirectly from claim 45 and claims 60-62 depend directly or indirectly from claim 58, Chuter does not anticipate any of the rejected claims. Consequently, none of the claims as submitted in the present application was, or would have been properly finally rejected on the grounds and art cited by the Examiner and so the finality of the rejection is

premature. Applicants respectfully request that the Examiner withdraw the final rejection.

Independent claims 45 and 58 have been amended to further emphasize the novelty of the claims over the prior art. Claims 45 and 58 as amended require, *inter alia*, a wire stent with at least one integral barb where the barb “points in a predetermined direction . . . [and] is unbent with respect to the wire.” (Emphasis added). Such wire stents have barbs that are “free of weakening due to bending,” in contrast with prior art stents that include bent barbs.


Chuter clearly contemplates attachment systems with non-integrally formed barbs and barbs that are bent. See e.g. Chuter, figures 7a-7b; col. 8, lines 51-54; col. 8, lines 64-65 (“[h]ooks 96 may be added, either by shaping them from the continuous cylinder, or by welding or gluing them on.” (emphasis added)). Such attachment systems are structurally and functionally different than the claimed stents where the barbs are integral with the wire and are unbent. Bending the barb with respect to the wire causes plastic deformation that may induce undesirable strains in, and weaken the stent. See e.g., ¶¶ 17-20 and 198-206. Consequently, stents as presently claimed are an improvement over the stents recited in Chuter.

Chuter fails to teach or disclose each and every structural limitation of independent claims 45 and 58 and therefore does not anticipate the claimed invention. Claims 46, 48-50, and 53 depend directly or indirectly from claim 45 and claims 60-62 depend directly or indirectly from claim 58. Accordingly, Chuter does not anticipate any of these claims. Applicants respectfully request that the rejection of Claims 45, 46, 48-50, 53, 58, and 60-62 be withdrawn and that the claims be allowed to pass to issuance. Early notification to such effect is earnestly solicited.

### SUMMARY

Because the prior art of record does not and would not have formed a proper basis for rejection, the final rejection in the first Office Action is premature. Applicants believe that the claims in the present application are patentable and that the application is in a condition for allowance. Applicants respectfully request that the finality of the Office Action be withdrawn and that the Examiner grant allowance of the application. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,



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